



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0385; FRL-10018-60]

Metaflumizone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the insecticide metaflumizone in or on multiple commodities which are identified and discussed later in this document. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2019-0385, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to

provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Acting Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. section 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the

instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2019-0385 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2019-0385, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the *Federal Register* of August 30, 2019 (84 FR 45702) (FRL-9998-15), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. section 346a(d)(3), announcing the filing of a pesticide petition (PP 8E8707) by BASF Corporation, P.O. Box 13528, Research Triangle Park, NC 27709. That document stated that BASF's petition (summarized by BASF

Corporation in docket ID EPA-HQ-OPP-2019-0385) requested that 40 CFR 180.657 be amended by establishing tolerances for residues of the insecticide metaflumizone (2-[2-(4-cyanophenyl)-1-[3-(trifluoromethyl)phenyl]ethylidene]-N-[4-(trifluoromethoxy)phenyl]hydrazinecarboxamide; E and Z isomers), in or on apple at 1.0 parts per million (ppm), apple, wet pomace at 3.0 ppm, coffee at 0.15 ppm, fruit, small, vine climbing, except fuzzy kiwi fruit, subgroup 13-07F at 5.0 ppm, grape, raisin at 10 ppm, lemon/lime subgroup 10-10B at 3.0 ppm, lemon/lime subgroup 10-10B, oil at 42 ppm, melon subgroup 9A at 1.0 ppm, orange subgroup 10-10A at 3.0 ppm, orange subgroup 10-10A, oil at 42 ppm, cattle, fat at 0.05 ppm, goat, fat at 0.05 ppm, horse, fat at 0.05 ppm, sheep, fat at 0.05 ppm, and milk, fat at 0.1 ppm. Although the petition summary did not request a tolerance on apple, wet pomace, the petition itself requested a tolerance on apple, wet pomace, so EPA included that commodity in the document published in the *Federal Register*. There were no substantive comments received in response to the notice of filing for this pesticide petition.

Based upon review of the data supporting the referenced petition, and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA has revised the tolerance levels and commodity definitions for several of the proposed commodities, established additional necessary tolerances, and deleted a number of established tolerances superseded by the newly established import tolerances. The reasons for these changes are explained in full detail in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special

consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for metaflumizone including exposure resulting from the tolerances established by this action. A summary of EPA’s assessment of exposures and risks associated with metaflumizone follows.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings and republishing the same sections is unnecessary; EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published a number of tolerance rulemakings for metaflumizone, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to metaflumizone and established tolerances for residues of that chemical. EPA is incorporating previously published sections from those rulemakings as described further in this rulemaking, as they remain unchanged.

Toxicological Profile. For a discussion of the Toxicological Profile of metaflumizone, see Unit III.A. of the October 30, 2015 rulemaking (80 FR 66795) (FRL-9934-88).

Toxicological Points of Departure/Levels of Concern. For a summary of the Toxicological Points of Departure/Levels of Concern used for the safety assessment, see Unit III.B. of the October 30, 2015 rulemaking.

Exposure Assessment. Much of the exposure assessment remains unchanged from the previous rulemaking, although some updates have occurred to accommodate exposures from the petitioned-for tolerances. The updates are discussed in this section; for a description of the rest of the EPA approach to and assumptions for the exposure assessment, see Unit III.C. of the October 30, 2015 rulemaking.

EPA's exposure assessments have been updated to include the additional exposure from imported apple, coffee, melon subgroup 9A, orange subgroup 10-10A, lemon/lime subgroup 10-10B, small vine climbing fruit subgroup 13-07F (except fuzzy kiwifruit), milk fat, and ruminant fat for the combined residues of metaflumizone (E-Z isomer ratio of >9:1). The acute and chronic dietary analyses for metaflumizone for this action assumed tolerance-level residues, 100% crop treated, and 2018 default processing factors when necessary, except for citrus juice, which used empirical processing factor for citrus juice. The modeled estimates of drinking water concentrations and the Agency's assessment of residential, or non-occupational exposure remain the same as in the October 30, 2015 rulemaking, as the residues on imported commodities do not impact the drinking water exposures or residential exposures. The Agency's position regarding cumulative risk also remains the same.

Safety Factor for Infants and Children. EPA continues to retain the Food Quality Protection Act (FQPA) safety factor of 10X for inhalation exposure scenarios, while continuing to conclude that there is reliable data showing that the safety of infants and children would be adequately protected if the FQPA SF were reduced from 10X to 3X for all oral exposure scenarios and reduced to 1X for dermal exposures. The reasons for that decision are articulated in Unit III.D. of the October 30, 2015 rulemaking.

Aggregate Risks and Determination of Safety. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the

appropriate PODs to ensure that an adequate MOE exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

The acute and chronic dietary estimates for metaflumizone were found not to be of concern for the U.S. general population and all population subgroups and are below the Agency's level of concern (LOC) (<100% of the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD), respectively). An acute endpoint of concern was not identified in the toxicological database for the general U.S. population including infants and children. Acute dietary risks for metaflumizone are below the Agency's LOC: 5.3% of the aPAD at the 95th percentile for females 13-49 years of age, the population group with the highest exposure; and chronic risks are below the Agency's LOC: 65% of the cPAD for children 1-2 years old, the most highly exposed population subgroup. Metaflumizone is classified as "Not Likely to be Carcinogenic to Humans." Therefore, EPA does not expect exposure to metaflumizone to pose a cancer risk.

Since metaflumizone is registered for uses that could result in short-term residential exposure, EPA evaluated the potential for short-term risk by aggregating chronic exposure through food and water with short-term residential exposures to metaflumizone. Since the LOC for the various routes of exposure differ, the aggregate risk estimates were calculated using the Aggregate Risk Index (ARI) approach (LOC for ARI < 1). The short-term aggregate assessment combined food + drinking water exposure with the highest potential residential post-application exposure (high-contact activity on turf). The aggregate ARIs are greater than 1; therefore, EPA concludes there is no short-term risk of concern. Although only short-term residential exposure is anticipated, the short-term assessment is protective of intermediate-term exposure since the short- and intermediate-term PODs/LOCs are identical.

Determination of Safety. Based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the U.S. general population, or to infants and children, from aggregate exposure to metaflumizone residues. More

detailed information on the subject action can be found at <http://www.regulations.gov> in the documents entitled “Metaflumizone: Human Health Risk Assessment in Support of Section 3 Registrations for Application of Metaflumizone to Pome Fruit (crop group (CG) 11-10) and Stone Fruit (CG 12-12); Updating the CG Designation for Citrus to 10-10 and Tree Nuts to 14-12; and Permitting Aerial Application to Citrus Fruits, Grapes, Tree Nuts, and Nurseries Containing Field-/Container-Grown Nonbearing Stone and Pome Fruit Trees,” dated September 29, 2015 (docket ID EPA-HQ-OPP-2014-0607), and “Metaflumizone: Human Health Risk Assessment in Support of Tolerances Without a U.S. Registration in/on Apple, Coffee, Melon Subgroup 9A, Orange Subgroup 10-10A, Lemon/Lime Subgroup 10-10B, Grape, Milk Fat, and Ruminant Fat,” dated December 7, 2020 (docket ID EPA-HQ-OPP-2019-0385).

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the October 30, 2015 rulemaking.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). Codex is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. Although EPA may establish a tolerance that is different from a Codex MRL, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

While Codex has not yet established MRLs on the commodities mentioned in this document, it has proposed MRLs in/on most of the relevant commodities. EPA notes that the

U.S. and Codex residue definitions differ in that the U.S. tolerance expression includes metaflumizone (E- and Z-isomers) and M320I04 while Codex includes only metaflumizone (E- and Z-isomers). EPA is harmonizing its U.S. tolerances with most of the proposed Codex MRLs for apple, coffee, grape, melon subgroup 9A, orange subgroup 10-10A, orange oil, raisin, milk fat, and fat (cattle, goat, horse, and sheep). EPA is not harmonizing the U.S. tolerance on lemon/lime subgroup 10-10B with the Codex MRL since the Codex MRL is less than that calculated by EPA using the submitted residue data and the OECD tolerance calculation procedure.

C. Revisions to Petitioned-For Tolerances

Based upon review of data and supporting materials for this petition, EPA is establishing tolerances for the following commodities requested using the Agency's preferred commodity terminology: instead of establishing a tolerance for coffee, as requested, the Agency is establishing a tolerance for coffee, green bean. In addition, based upon supporting data and harmonization with proposed Codex MRLs, the Agency is establishing a tolerance level lower than requested for Apple at 0.9 ppm, and tolerance levels higher than requested for grape, raisin at 13 ppm; lemon/lime subgroup 10-10B, oil at 100 ppm; and orange subgroup 10-10A, oil at 100 ppm. Further, since importation of ruminant commodities is also a probability and based on the livestock dietary burdens, EPA is also establishing tolerances for milk fat and ruminant fat tolerances in or on cattle, fat at 0.15 ppm; goat, fat at 0.15 ppm; horse, fat at 0.15 ppm; sheep, fat at 0.15 ppm; and milk, fat at 0.6 ppm.

V. Conclusion

Therefore, tolerances are established for residues of the insecticide metaflumizone (2-[2-(4-cyanophenyl)-1-[3-(trifluoromethyl)phenyl]ethylidene]-N-[4-(trifluoromethoxy)phenyl]hydrazinecarboxamide; E and Z isomers), in or on apple at 0.9 parts per million (ppm); apple, wet pomace at 3 ppm; coffee, green bean at 0.15 ppm; grape, raisin at 13 ppm; grapefruit subgroup 10-10C at 0.04 ppm; lemon/lime subgroup 10-10B at 3 ppm;

lemon/lime subgroup 10-10B, oil at 100 ppm; melon subgroup 9A at 1 ppm; orange subgroup 10-10A at 3 ppm; orange subgroup 10-10A, oil at 100 ppm; cattle, fat at 0.15 ppm; goat, fat at 0.15 ppm; horse, fat at 0.15 ppm; milk, fat at 0.6 ppm; and sheep, fat at 0.15 ppm. In addition, the existing tolerance for “fruit, pome, group 11-10,” is amended to clarify that that entry now excludes apple, due to the establishment of a separate apple tolerance in this rulemaking and the existing tolerance for grape is amended to raise the tolerance level from 0.04 ppm to 5 ppm. Finally, EPA is removing the tolerance for “fruit, citrus, group 10-10” because it is superseded by the newly established tolerances for each of the fruit, citrus, group 10-10 subgroups.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997) or Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. section 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. section 601 *et*

seq.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the National Government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. section 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. section 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. section 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. section 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 8, 2021.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.657:

a. Designate paragraph (a) introductory text as paragraph (a)(1) and revise newly designated paragraph (a)(1) introductory text;

b. In the table in newly designated paragraph (a)(1):

i. Add a heading for the table;

ii. Add entries for “Apple,” “Apple, wet pomace,” and “Coffee, green bean” in alphabetical order;

iii. Remove the entries for “Fruit, citrus, group 10-10,” “Fruit, pome, group 11-10,” and “Fruit, stone, group 12-12”;

iv. Add the entry “Fruit, pome, group 11-10, except apple” in alphabetical order;

v. Revise the entry for “Grape”;

vi. Add entries for “Grape, raisin,” “Grapefruit subgroup 10-10C,” “Lemon/lime subgroup 10-10B,” “Lemon/lime subgroup 10-10B, oil,” “Melon subgroup 9A,” “Orange subgroup 10-10A,” and “Orange subgroup 10-10A, oil” in alphabetical order; and

vii. Revise footnote 1; and

c. Add paragraph (a)(2).

The additions and revisions read as follows:

§ 180.657 Metaflumizone; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide metaflumizone, including its metabolites and degradates, in or on the commodities listed in table 1 to this paragraph (a)(1). Compliance with the tolerance levels specified in this paragraph (a)(1) is to be determined by measuring only the sum of metaflumizone (E and Z isomers; 2-[2-(4-

cyanophenyl)-1-[3-(trifluoromethyl) phenyl]ethylidene]-*N*-[4-(trifluoromethoxy)phenyl] hydrazinecarboxamide) and its metabolite 4-{2-oxo-2-[3-(trifluoromethyl) phenyl]ethyl}-benzonitrile, calculated as the stoichiometric equivalent of metaflumizone, in or on the following commodities:

Table 1 to Paragraph (a)(1)

Commodity	Parts per million
* * * * *	
Apple	0.9
Apple, wet pomace	3
Coffee, green bean ¹	0.15
* * * * *	
Fruit, pome, group 11-10, except apple	0.04
Grape	5
Grape, raisin	13
Grapefruit subgroup 10-10C	0.04
Lemon/lime subgroup 10-10B	3
Lemon/lime subgroup 10-10B, oil	100
Melon subgroup 9A ¹	1
* * * * *	
Orange subgroup 10-10A	3
Orange subgroup 10-10A, oil	100
* * * * *	

¹There are no U.S. registrations for this commodity as of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

(2) Tolerances are established for residues of the insecticide metaflumizone, including its metabolites and degradates, in or on the commodities listed in table 2 to this paragraph (a)(2). Compliance with the tolerance levels specified in this paragraph (a)(2) is to be determined by measuring only metaflumizone (E and Z isomers; 2-[2-(4-cyanophenyl)-1-[3-(trifluoromethyl) phenyl]ethylidene]-*N*-[4-(trifluoromethoxy)phenyl] hydrazinecarboxamide) in or on the following animal commodities:

Table 2 to Paragraph (a)(2)

Commodity	Parts per million
Cattle, fat	0.15
Goat, fat	0.15
Horse, fat	0.15
Milk, fat	0.6

Sheep, fat	0.15
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